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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,320	06/12/2001	Ajay Hasmukhlal Upadhyay	RD 01022	5176
7590 01/26/2005 KEVIN E. MC VEIGH RHODIA INC. 259 PROSPECT PLAINS ROAD CRANBURY, NJ 08512			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/879,320

**Applicant(s)**

UPADHYAY, AJAY HASMUKHLA

**Examiner**

Lakshmi S Channavajjala

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-8,31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8,31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of amendment and remarks of 10-12-04 is acknowledged.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-12-04 has been entered.

Claims 1-4, 6-8, 31 and 33-36 are pending in the instant application.

#### ***Claim Rejections - 35 USC § 103***

Claims 1-4, 6-8, 31 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,798,725 to Patel (Patel).

Patel teaches a pharmaceutical composition for oral administration comprising a particulate mixture of an active drug, polyvinylpyrrolidone and a carboxyvinyl polymer (abstract, col. 6, lines 61-68). The particulate mixture of Patel is a flowable and is composed of particles that have a tendency to moderately adhere and yet move (paragraph bridging col. 2-3). Patel teaches PVP in an amount of 5% to 96% (col. 4, lines 10-21), and active agent in an amount of 0.01% to 90% (col. 6, lines 55-60). Patel also teaches that the particles have a size such that they pass through 60 mesh, which accordingly to the instant specification is 250microns and thus is within the claimed range. According to claim 1, <30% of the particles

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have a size greater than 425 microns and >80% of the particles have a size greater than 45 microns. In other words, the size of the instant particles is between 45 and 425 microns, which includes 250 microns. Example 7 of Patel is directed to a composition of particulate mixture of guaifenesin together with PVP, talc, zinc stearate and Carbopol.

Patel fails to teach the following claim limitations: exact percentages of the particles of specific sizes, agglomerated mixture, percentages of the amounts of guaifenesin, specific solubilizer maltodextrin and the claimed flow rate. However, Patel teaches a particulate mixture of the same active ingredient and binder as claimed and the particle sizes used by Patel, as explained above, in the same range as claimed. Patel also suggests high amounts of active agent, as high as 90%. Further, the invention of Patel is also directed to a particulate and yet flowable composition (col. 10, lines 37-49), so as to obtain a sustained release of the drug. Furthermore, Patel also suggests addition of the pharmaceutical excipients such as silicon dioxide, stearic acid, talc and other conventional additives (col. 7). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to optimize the amounts of particulate guaifenesin, PVP and other additives, choose the particle sizes and the excipients in the composition of Patel, so as to achieve the desired flow rate of the particle mixture (of active and the excipients) and thus achieve a desired release pattern.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-4, 6-8, 31 and 33-36 have been considered but are moot in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
January 21, 2005